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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,689	08/28/2001	Felix Franks	INHA0012ICO/US	8127

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NEIFELD IP LAW, PC
2001 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER
RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1654	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/939,689	Applicant(s) FRANKS ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,28,29,32-34,38,39,41,43,46,47,52 and 54-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,28,29,32-34,38,39,41,43,46,47,52 and 54-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *07/479,939* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 3, 2003 has been entered.

2. The appropriate maintenance fees for U.S. Patent No. 5,098,893 have been paid, and therefore the reissue procedures are available for this patent.

3. The assent of the assignee under 37 CFR 1.172 filed October 3, 2002 is approved.

4. The original patent was actually surrendered during the prosecution of the parent reissue application 09/270,791, and therefore the requirement set forth in 37 CFR 1.178(a) has been satisfied.

5. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,098,893 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

6. The reissue declaration filed October 3, 2002 is approved. However, in view of the subsequent amendments which have been made to this application, Applicants are reminded of

the likelihood that a supplemental reissue oath or declaration will have to be filed before this application can be allowed. See MPEP 1444.

7. In the amendment filed February 12, 2002, page 2 of the amendment, a notice of more than one reissue application was inserted as the first paragraph of the specification. The status of reissue application number 09/270,791 should be updated in this paragraph.

8. Claims 38, 39, 41, and 54 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: There is no original disclosure supporting the exclusion of rennin as is recited in instant claims 39 and 41. Rennin is not mentioned in the disclosure, and silence in the specification is not support for a negative claim limitation. See Ex parte Grasselli, 231 USPQ 393, aff'd on reconsideration 231 USPQ 395 (Bd. App. 1983). Accordingly, the negative claim limitations in these claims constitute new matter. Claims 38 and 54 recite dissolution in an aqueous solution having a pH of about 7, which embraces dissolution at slightly acidic pHs. However, there is no original disclosure in the specification of dissolution at slightly acidic pHs, the only pHs recited in the sections of the specification cited by Applicants ranging from 7.0 to 7.6. Accordingly, the pH range recited in claims 38 and 54 is new matter.

9. Claims 38, 39, 41, and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the exclusion of rennin as is recited in instant claims 39 and 41. Rennin is not mentioned in the disclosure, and silence in the specification is not support for a negative claim

limitation. See Ex parte Grasselli, 231 USPQ 393, aff'd on reconsideration 231 USPQ 395 (Bd. App. 1983). Claims 38 and 54 recite dissolution in an aqueous solution having a pH of about 7, which embraces dissolution at slightly acidic pHs. However, there is no original disclosure in the specification of dissolution at slightly acidic pHs, the only pHs recited in the sections of the specification cited by Applicants ranging from 7.0 to 7.6. Accordingly, the pH range recited in claims 38 and 54 is not supported by the original disclosure of the invention.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 28, 29, 32-34, 38, 39, 41, 43, 46, 47, 52, and 54-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-45, 57, and 63-91 of copending Application No. 09/939,688. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '688 application clearly anticipate instant claims 26, 28, 29, 32-34, 39, 41, 43, 46, 47, 52, 55, and 64-68 (see, e.g., claims 57, 65, 72, 83, and 84). The '688 application claims forming the compositions claimed in instant claims 38 and 54 (see, e.g., claims 74 and 76), with the exception that the '688 application does not claim a dissolution pH. It would have been obvious to one of ordinary skill in the art to determine all operable and optimal dissolution pHs

for the claimed compositions of the '688 application because pH is an art-recognized result-effective variable which is routinely determined and optimized in the chemical solution and pharmaceutical arts. With respect to instant claims 56-63, the compositions recited in the instant claims, including the tableted forms, are claimed in the '688 application, although the '688 application does not claim administering these particular biologically active materials stored in the compositions. It would have been obvious to one of ordinary skill in the art to administer the biologically active materials stored in the claimed compositions of the '688 application because most of the stored biologically active materials are known to have desirable pharmacological properties and because the '688 application claims that the biologically active materials are storage-stable in the claimed compositions, i.e. their desirable pharmacological properties would have been expected to be retained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 26, 28, 29, 43, 46, and 52 are rejected under 35 U.S.C. 102(e) as Koyama et al. Koyama et al teach stabilized water-soluble dry solid compositions comprising proteinaceous bioactive substances, for example hormones. Aqueous solutions of the proteinaceous bioactive substances are combined with aqueous solutions a polysaccharide composed mainly of maltotriose units at a ratio of polysaccharide:protein of preferably 1 to 10,000. The weight ratio of the polysaccharide to the substance is at least 0.5, preferably from 1.0 to 10000. The combined solutions are then dried, either by conventional procedures at reduced pressure and a

temperature below 30°C, or else by freeze-drying. In one series of examples, greater than 90% of activity is retained after storage at 37°C for one month, which is consistent with Applicants' requirement for at least 53% retained activity after storage for 8 weeks at 25°C. The dry solid can be formed into a tablet and can be used for external of internal administration to prevent or treat human diseases. See, e.g., the Abstract; column 2, lines 10-24 and 38-66; Experiment 3; and the Examples. In view of the similarity in the components of the compositions and the retained activity of the compositions, the compositions of Koyama et al are deemed inherently to have the same storage stability, and T_g claimed by Applicants and are deemed to anticipate the compositions claimed by Applicants. Sufficient evidence of similarity between the compositions of Koyama et al and Applicants' claimed compositions is deemed to be present to shift the burden to Applicants to show that their claimed compositions are unobviously different than those of Koyama et al. Note that even a patentable difference in the process of making does not necessarily impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

13. Claims 32-34, 47, and 55-68 are rejected under 35 U.S.C. 103(a) as being obvious over Koyama et al as applied against claims 26, 28, 29, 43, 46, and 52 above, and further in view of Applicants' admission of the prior art at column 1, lines 59-62; column 4, lines 57 - 66; and column 5, lines 3-8. Koyama et al do not teach any examples in which conventional drying procedures at reduced pressure and a temperature below 30°C are used. However, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the dried compositions of Koyama et al using conventional drying procedures at reduced pressure and at a temperature below 30°C because as admitted by Koyama et al, such drying

procedures are conventional and are suitable for producing Koyama et al's desired products, and because as admitted by Applicants at column 1, lines 59-62, of the application, freeze-drying is costly in capital and energy and is irreproducible. Regardless of the method used to produce the dried compositions of Koyama et al, the dried compositions of Koyama et al would have been expected to have a T_g greater than 20°C because as admitted by Applicants at column 4, lines 59-60, the T_g for maltotriose is 76°C and as admitted by Applicants at column 5, lines 3-8, the T_g for water-soluble or water-swellable synthetic polymers is a function of molecular weight. Accordingly, the T_g for Koyama et al's polysaccharide composed mainly of maltotriose units would have been expected to be even higher than the 76°C for a maltotriose monomer. The T_g for Koyama et al's proteinaceous bioactive substances would also have been expected to be relatively high because the proteins are also water-soluble polymers of relatively high molecular weight. Even if Koyama et al's dried compositions were to contain several percent residual water after drying, in view of Applicants' admitted rule-of-thumb at column 4, lines 63-65, of an approximately 6°C decrease in T_g for each percent of moisture added, the dried compositions would still have a T_g greater than 20°C in view of the relatively high T_g of the major components. Koyama et al do not teach drying proteins such as enzymes, transport proteins, immunoglobins, and blood clotting factors. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to dry proteins such as enzymes, transport proteins, immunoglobins, and blood clotting factors in the methods of Koyama et al because these are known proteinaceous substances which it would be desirable to be able to store and because Koyama et al's method is applicable to all proteinaceous substances which exhibit a bioactivity in vivo.

14. Applicant's arguments filed April 3, 2003 have been fully considered but they are not persuasive.

The rejections under 35 U.S.C. 251 and 35 U.S.C. 112, first paragraph, are maintained for the reasons of record.

The obviousness-type double patenting rejection based upon Reissue Patent No. 37,872 (which issued based upon reissue application 09/270,791) is overcome by the terminal disclaimer filed April 3, 2003, which has been approved. The provisional obviousness-type double patenting rejection based upon copending reissue application 09/939,688 is maintained for the reasons of record. The examiner expects to convert this provisional rejection into an actual obviousness-type double patenting rejection, to which Applicants will be required to respond, when the '688 application finally issues.

The rejections based upon Koyama et al are maintained. Applicants' arguments duplicate those set forth in the amendment filed October 3, 2002 in this application, and the examiner maintains his position with respect to these claims for the reasons of record. New claims 55-68 are copied from copending reissue application 09/939,688. These claims continue to be rejected for the reasons set forth during the prosecution of the '688 application.

15. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 30, 2003